REMARKS

This Amendment is being filed in response to the Office Action mailed on December 4, 2008.

Claim 38 has been amended to more specifically point out that the present invention contains at least two bupropion containing pellet systems, namely a first pellet comprising a sustained release component containing bupropion and a second pellet comprising an enteric release component containing bupropion. Additionally, the claimed invention also comprises a third component containing immediate release bupropion. Claims 40-41 have also been amended to maintain proper antecedent basis in accordance with the amendment to claim 38. Support can be found in the claims as originally filed and in the specification at paragraphs 0035-0055 of the published application (see US Pub. App. 2003/0161874). No new matter is added by the amended claims.

In the Office Action the Examiner rejected claims 36-43 and 46-50 (based on the pending claims Applicant submits that the Examiner intended claims 38-43 and 46-50) under 35 U.S.C. §103(a) as being unpatentable over US Published Patent Application No. 2001/0046964 (hereinafter "the '964 application). The Examiner also rejected claims 38-50 under 35 U.S.C. § 103(a) as being unpatentable over the '964 application in view of US 6,270,805 (hereinafter "the '805 patent").

Claims 38-50 are directed to a three component dosage form that comprises: 1) an immediate release bupropion component; 2) a first pellet comprising an enteric release component which comprises bupropion and a pH dependent polymer; and 3) a second pellet comprising a sustained release component which comprises bupropion and a water insoluble polymer. Applicants have discovered that the three component system will allow once a day dosing of bupropion without the major peaks or spikes in plasma concentration that can result in adverse side effects.

Applicants respectfully submit that the newly amended claims are patentable over the teachings of the '964 application. The '964 application teaches a multi-particulate timed pulsed drug delivery system wherein a population of particles are coated with a single controlled release system, namely, a first coating comprising an enteric coating **and** a second coating comprising an enteric material and a water insoluble material, wherein both coating are applied to a single

active containing core. This dual modified release coating system is different from the presently claimed invention which requires a first pellet comprising bupropion in an enteric component and a second pellet comprising bupropion in a sustained release component, and a third component comprising an immediate release component of bupropion, wherein the immediate release component may be, but is not limited to, a third separate immediate release bupropion pellet, dispersed as a powder in a capsule or tablet formulation, or coated over either of the first two pellet systems. The three component system, wherein the enteric component and the sustained release component are located on separate and distinct pellets, is not disclosed or suggest by the '964 application.

The Examiner has noted that the '964 application teaches "approximately 197.5 grams of the active agent" (see Office Action page 3), Applicants submit that the '964 application teaches a method of preparing dosage forms that begins with 197.5 **grams** of raw material in mixture, not 197.5 **mg** in the final dosage form. Therefore applicants submit that the claim element of 75 to 450 mg of bupropion is not disclosed or suggested by the '964 application.

The '805 patent does not disclose dosage forms containing three components containing bupropion, namely an immediate release component, a sustained release component and an enteric release component. Furthermore, there is no specific example in the '805 patent that discloses the use of bupropion, only a single reference to the possible use of bupropion because it is a water soluble drug. See the '805 patent at col. 3, lines 5-10. Further, the use of ethylcellulose in the '805 patent is as a "polymeric binder" combined with the diltiazem hydrochloride and deposited on the inactive core prior to applying the delayed release coating or enteric release coating (see col. 3, lines 15-20). In contrast the present claims recite a "water insoluble coating polymer" as part of the sustained release component. The coating polymer is used to control the release of the bupropion from the sustained release component, not to bind the active to the core as taught in the '805 patent. Therefore the polymeric binder of the '805 patent is different from the water insoluble coating polymer as recited in the claims of the present invention.

Because neither the '805 patent or the '964 patent teach the specific coating systems or pellet systems of the present invention, the teaching cited by the Examiner on page 5 referring to preparing pellets or tablets does not render obvious the claims of the present invention.

Furthermore, there is no teaching or suggestion in the '964 application to combine an immediate release coating with a multiple pellet system wherein the pellets contain different coating systems, namely, one with a sustained release systems and one with an enteric release system as recited in claim 38 of the present application.

Therefore, applicants submit that claim 38 and the claims which depend therefrom are not disclosed or suggested by the cited prior art and it is requested that the above 103(a) rejection be withdrawn.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the pending claims in the above-identified application are patentable over the art of record. Early and favorable action is earnestly solicited.

Respectfully submitted,

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